

REMARKS

In the pending Final Office Action (FOA), the Examiner has again rejected claims 1-65 over the Casey, Cohen, and/or Severns references. After reviewing the Office Action's analysis, it is believed that they do not anticipate or render the claims obvious. Further reconsideration of the present claims, entry of new claims 66 and 67, and withdrawal of the pending rejections are respectfully requested.

Claims 64-65 Were Not Properly Addressed in the FOA and Are Not Anticipated by Casey

In their previous response, Applicants added new claims 64-65 (along with new claim 63) to more fully define the subject matter of the present application. Claim 64 (depending from independent claim 1) provides that the elongate member has one or more exterior surfaces and the reinforcement component is placed on the exterior surfaces. Claim 65 (amended to depend from independent claim 1) recites that the elongate member has one or more exterior surfaces and the reinforcement component is deposited on the exterior surfaces. New claims 64-65 were not sufficiently addressed in the FOA and are not anticipated by or obvious over Casey.

In the FOA, claims 64 and 65 were grouped together with independent claim 1 and other dependent claims as anticipated by Casey. However, the FOA provided no discussion or explanation particular to claims 64 and 65, either under the anticipation analysis or in the Response to Arguments section. Accordingly, it is respectfully believed that a proper rejection of these claims has not been made.

Claims 64 and 65 are not anticipated or rendered obvious by the Casey reference, or any of the other cited references. Casey does not teach a reinforcement component placed or deposited on the exterior surface of the elongate member. As explained in the previous response,

Casey teaches a homogenous mixture of different materials. The materials are mixed together, or one impregnated with another, to create a polymeric composition. There certainly is no teaching or suggestion of placing or depositing one of the materials to the exterior surface of another. Instead, Casey teaches the opposite idea of mixing materials together. None of the other cited references fill this void left by Casey. Applicant respectfully asserts that the anticipation rejection of claims 64-65 over the Casey reference should be withdrawn and these claims should be allowed.

Arguments in the FOA are Off Point

In responding to remarks made in Applicants' previous response, the FOA quotes a phrase from Casey regarding the combination of a bioabsorbable polymer and a reinforcing fiber (which may or may not be bioabsorbable), and then goes on to state that "[o]ne is not necessarily an ingredient of another." (FOA, p. 5). This statement appears to address dependent claim 63, which recites that the elongate member is formed of a material, and the reinforcement component is not an ingredient of the material. While it is agreed that Casey's polymer is not necessarily an ingredient of its reinforcing fiber, and vice versa, the FOA appears to miss the point. In the FOA and previous Office Action, Casey's bone plate was compared to the claimed elongate member and Casey's reinforcing fiber to the claimed reinforcement component. Under that analysis, Casey cannot anticipate or render obvious claim 63, because Casey's reinforcing fiber is undoubtedly an ingredient in the bone plate. In other words, even if Casey's reinforcing fiber is not an ingredient of its polymer, it obviously is an ingredient of the composition that makes up the plate. The Casey polymer is not the plate, but is one component of the plate along with the fiber. The FOA additionally stated that Casey's fibers are "combined in such a way as

to vary or transfer stiffness as the bone heals.” (FOA, p. 5). Assuming that to be true, that fact does not apply to the particular structural elements and their arrangements recited in the claims.

New Claims

New dependent claims 66 and 67 are being offered in this response, to more fully define subject matter for which protection is sought. Claim 66 is supported at least by the descriptions of materials in paragraphs 0028-0033 and Figures 1 and 2. Claim 67 is supported at least by Figure 1 and related text. The Casey reference does not disclose the recited structure of the bone plate, including flexibility voids as well as fastener openings, nor does it disclose the deposit of the reinforcement component on the bone plate as provided in claim 66. It also does not show or suggest part of an elongate member within a reinforcing component, and part of it outside the reinforcing component.

The Claims Are Not Anticipated by the Casey Reference

The arguments provided in the previous response remain valid and on point. For the sake of brevity, they are not being repeated verbatim. However, aspects of them are noted below for the convenience of the Examiner, and the entirety of those arguments is incorporated herein by reference. No concession of any argument is being made.

As noted above, the FOA compared the Casey plate 1 to the recited elongate member, and Casey’s reinforcing fiber to the recited biodegradable reinforcing component. There is no disclosure in Casey that its plate 1 (shown in its Figures 4-7) allows translational or rotational movement of bone portions, as recited in claim 1. The example of screw attachment in Casey’s Figure 7 shows screws firmly seated in the plate, so that it cannot move with respect to each

portion of bone 4, and the portions cannot move with respect to each other. The bonding example suggested in the text also results in the plate and both bone portions all fixed together. Device 1 immobilizes the bone pieces to “allow the best possible chance for uniform healing of the fracture.” Of course, when the fracture is healed, the bone pieces also cannot move with respect to each other, and movement of pieces of a long bone as in Casey is undesirable at any time. Thus, Casey does not show or suggest any respective movement of bone pieces.

Claim 1 recites an elongate member and a reinforcing component that is engaged to the elongate member. The FOA and previous Actions have assumed that Casey’s “reinforcement fiber” mixed or impregnated with polymer is thereby “engaged” to an elongated member. This view misses the fact that in Casey, there is no plate until after the reinforcing fiber is mixed with the polymer and the combination sets as a plate. It is not possible to differentiate the reinforcing fiber from the plate because under Casey’s instructions, one cannot have a plate without the fiber. Assuming for argument’s sake that mixing or impregnating with polymer is an “engaging,” then Casey’s “reinforcement fiber” is only engaged to polymer, not an “elongate member” as recited in claim 1. The fiber is not engaged to an elongate member.

As to claim 38, the Office Action does not provide an analysis of the “means” language used. Respectfully, it must be determined whether that language invokes Section 112, paragraph 6, and if so, the appropriate limitation is to be considered the corresponding structures, materials or acts in the specification and equivalents thereof. MPEP 2181 (citing *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994)). Without those considerations, a case of anticipation of claim 38 cannot be made. Moreover, as noted above there is nothing in Casey’s device 1 that allows movement of bone portions relative to each other.

Claims 17-21 Are Not Obvious over the Casey and Cohen References

Not all features of these claims are shown, at least for the reasons noted above with respect to claim 1. The combination of Casey and Cohen also does not show a portion configured to resist deformation as recited in claim 18. The Office Action did not identify such a portion, and Cohen's plate is designed to deform throughout its length by virtue of the slots placed along the whole length.

The Casey and Cohen references also teach away from their combination as proposed. Casey's device 1 is designed for uniform fracture healing, which needs the immobilization of a rigid device. Cohen, on the other hand, teaches a plate that is designed to be flexible so as to provide some stabilization to vertebrae while allowing easy attachment and accommodate the curved configuration of the spinal column. Further, Casey teaches the value of consistency and uniformity in the material used for device 1 and its characteristics, while Cohen teaches non-uniformity in the form of slots to enable use of its plate. Since Casey directs one of ordinary skill toward immobility and constancy, and Cohen directs toward adaptability, flexion and variation, they do not suggest a reasonable chance of success in the combination.

Claims 24-32, 35, 47-52 and 57-62 Are Not Obvious over Casey and Severns

Each of claims 24-32 and 35 is dependent from independent claim 1, and so all of the features of these claims are not shown in the combination of these references as discussed above.

The combination of Casey and Severns also do not show a spinal rod as recited in claim 25. Severns' item 20 is an intramedullary nail (paragraph 0040). Severns also indicates that it concerns bone plates (paragraph 0002), but does not describe or refer to a spinal rod or any use with the spine at all.

Severns does not show any reinforcing material that encases a portion of an orthopedic rod, as recited in claim 29. The Office Action alleged that items 46 of Severns were “reinforcing material.” However, Severns’ items 46 do not encase any part of intramedullary nail 20. Rather, each is a sleeve for a fastener. Severns also does not show a portion of an orthopedic rod configured to allow the rod to be deformed, as recited in claim 30. An intramedullary nail as in Severns is inserted into a medullary canal to assist healing of a long bone, and thus deformation of it is undesirable. Severns does not disclose any deformable portion of its nail.

Independent claim 47 includes features of claim 1 and other claims discussed above that are not disclosed in Casey or Severns. The remarks given above, including those relative to the recited elongate member and reinforcing component and their relationship, as well as those concerning the absence of an orthopedic rod, are equally applicable with respect to claim 47.

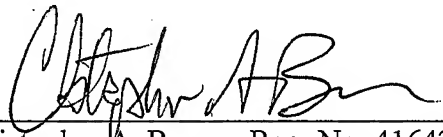
Claims 48-52 and 57-62 depend from claim 47, and are allowable on that basis and/or on their own merit. For example, claim 50 recites that the elongate member allows restricted movement of bone portions after a reinforcing component biodegrades. As discussed above with respect to claim 1, Casey’s device 1 provides for uniform healing. No movement of the bone portions is possible when device 1 is placed so that uniform healing can occur, and once the healing has occurred no further movement of the parts of the healed bone is possible. Similarly, Severns’ intramedullary nail holds bone parts fast with respect to each other on implantation, and when the long bone has healed, there is no possibility of its parts moving with respect to each other. The remarks given above with respect to claims 11, 25, and 29 apply equally to claims 57, 58, and 60, respectively. Method claim 62 includes all features of claim 47, and is not obvious for at least the reasons given above.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede any basis for the rejections in the Office Action but are simply provided to address the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken in the Office Action that are not specifically addressed herein. Further, no limitation of the claims is intended by any of the remarks herein. The claims are intended to have the full scope to which their language entitles them, including equivalents.

In light of the current amendments and remarks, reconsideration and allowance of all of the pending claims is respectfully requested. The Examiner is invited to call the undersigned to discuss any further issues that may remain.

Respectfully submitted,

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